Arcutis' ZORYVE® (roflumilast) Cream 0.15% Receives Strong Recommendation in American Academy of Dermatology Updated Guidelines for Adult Atopic Dermatitis

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- The American Academy of Dermatology (AAD) provided evidence-based recommendation for the use of ZORYVE® (roflumilast) cream 0.15% in adults with mild to moderate atopic dermatitis (AD)
- Recommendation reflects ZORYVE's proven efficacy, safety, and tolerability as a next-generation, steroid-free, topical phosphodiesterase-4 (PDE4) inhibitor
- Among newly evaluated branded topical therapies, ZORYVE is the only treatment with a strong recommendation for adults with mild to moderate atopic dermatitis in AAD's focused guideline update
- ZORYVE is the first FDA-approved branded topical PDE4 inhibitor indicated for AD, plaque psoriasis, and seborrheic dermatitis
- AD impacts over 16 million adults in the United States

WESTLAKE VILLAGE, Calif, June 26, 2025 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company dedicated to developing meaningful innovations in immuno-dermatology, today announced that ZORYVE® (roflumilast) cream 0.15% has received a strong recommendation in the focused guideline update for the management of adult AD from AAD. The recommendation highlights ZORYVE's ability to deliver clinically meaningful improvements in pruritus and disease severity, its favorable tolerability profile, and low rates of treatment discontinuation, offering adults and pediatric patients 6 years of age and older with mild to moderate AD an effective, non-steroid option for daily disease management.

"The AAD's focused update highlights therapies that meet rigorous standards for efficacy, safety, and tolerability for adults living with AD," said Patrick Burnett, MD, PhD, FAAD, chief medical officer at Arcutis. "The inclusion of ZORYVE in these recommendations validates what healthcare professionals have already experienced with ZORYVE in their practice – a next-generation, steroid-free topical that delivers meaningful improvement for people with AD. It marks important progress in providing individuals with AD and their healthcare providers evidence-based choices that are suitable for all areas, including sensitive and hard-to-treat areas of the body."

The AAD's strong recommendation helps guide clinicians and patients toward treatments that deliver clinically meaningful improvements in disease severity while being safe and well tolerated for long-term use. The focused update incorporates newly Food and Drug Administration (FDA)-approved topical and biologic therapies into existing guidelines to ensure that the dermatology community has access to the most current, evidence-based recommendations for managing this chronic condition.

For more information on ZORYVE, including full prescribing information, please visit www.zoryve.com.

About Atopic Dermatitis
AD is the most common type of eczema, affecting approximately 9.6 million children and 16.5 million adults in the United States. AD is a chronic, relapsing, and genetically predisposed inflammatory skin disease that has unique clinical presentations across the lifespan. The disease typically appears as a red, intensely itchy rash that can occur anywhere on the body. It presents differently in infants, children, and adults.

About ZORYVE® (roflumilast)
ZORYVE is the first and only branded topical therapy for three major inflammatory dermatoses — AD, seborrheic dermatitis, and plaque psoriasis. ZORYVE is a next generation topical PDE4 inhibitor. PDE4, an established target in dermatology, is an intracellular enzyme that increases the production of pro-inflammatory mediators and decreases production of anti-inflammatory mediators.

ZORYVE (roflumilast) cream 0.3% is approved by the FDA for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older. ZORYVE (roflumilast) cream 0.15% is approved by the FDA for the topical treatment of mild to moderate AD in patients 6 years of age and older. In 2024, ZORYVE cream 0.15% was awarded *Glamour's* Beauty and Wellness Award for "Eczema Product." ZORYVE (roflumilast) topical foam 0.3% is uniquely formulated for use anywhere on the body, including hair-bearing areas, and is indicated for treatment of plaque psoriasis of the scalp and body in patients 12 years of age and older, as well as seborrheic dermatitis in patients 9 years of age and older. Recently, both ZORYVE cream 0.3% and ZORYVE foam 0.3% were awarded the National Psoriasis Foundation's Seal of Recognition —the first FDA-approved product to receive the honor.

Investigational ZORYVE (roflumilast) cream 0.05% for the topical treatment of mild to moderate AD in children 2 years to 5 years old is under review by the FDA with a Prescription Drug User Fee Act (PDUFA) target action date of October 13, 2025.

INDICATIONS
ZORYVE topical foam, 0.3%, is indicated for the treatment of plaque psoriasis of the scalp and body in adult and pediatric patients 12 years of age and older.

ZORYVE topical foam, 0.3%, is indicated for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

ZORYVE cream, 0.3%, is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in adult and pediatric patients 6 years of

age and older.

ZORYVE cream, 0.15%, is indicated for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older.

IMPORTANT SAFETY INFORMATION
ZORYVE is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

Flammability: The propellants in ZORYVE foam are flammable. Avoid fire, flame, and smoking during and immediately following application.

The most common adverse reactions (≥1%) for ZORYVE foam 0.3% for plaque psoriasis include headache (3.1%), diarrhea (2.5%), nausea (1.7%), and nasopharyngitis (1.3%).

The most common adverse reactions (≥1%) for ZORYVE foam 0.3% for seborrheic dermatitis include nasopharyngitis (1.5%), nausea (1.3%), and headache (1.1%).

The most common adverse reactions (≥1%) for ZORYVE cream 0.3% for plaque psoriasis include diarrhea (3.1%), headache (2.4%), insomnia (1.4%), nausea (1.2%), application site pain (1.0%), upper respiratory tract infection (1.0%), and urinary tract infection (1.0%).

The most common adverse reactions (≥1%) for ZORYVE cream 0.15% for atopic dermatitis include headache (2.9%), nausea (1.9%), application site pain (1.5%), diarrhea (1.5%), and vomiting (1.5%).

Please see full **Prescribing Information** for ZORYVE cream and full **Prescribing Information** for ZORYVE foam.

About Arcutis
Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a commercial-stage medical dermatology company that champions meaningful innovation to address the urgent needs of individuals living with immune-mediated dermatological diseases and conditions. With a commitment to solving the most persistent patient challenges in dermatology, Arcutis has a growing portfolio of advanced targeted topicals approved to treat three major inflammatory skin diseases. Arcutis' unique dermatology development platform coupled with our dermatology expertise allows us to invent differentiated therapies against biologically validated targets, and has produced a robust pipeline with multiple follow-on clinical programs for a range of inflammatory dermatological conditions including AD and alopecia areata. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn, Facebook, Instagram, and X.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. For example, statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on the Company's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding the potential for ZORYVE cream 0.15% as a treatment for adult AD patients. These statements are subject to substantial known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. Risks and uncertainties that may cause our actual results to differ include risks inherent in our business, reimbursement and access to our products, the impact of competition and other important factors discussed in the "Risk Factors" section of our Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on February 25, 2025, as well as any subsequent filings with the SEC. Any forward-looking statements that the company makes in this press release are made pursuant to the Private Securities Litigation Reform Act of 1995, as amended, and speak only as of the date of this press release. Except as required by law, we undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

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